

APR 25 2003

ARMSTRONG, WESTERMAN & HATTORI, LLP
725 K. STREET, N.W.
SUITE 1000
WASHINGTON, D.C. 20006

13

| | |
|----------------------------|---------------------|
| In re Application of | : |
| HOSOKAWA et al | : |
| Serial No.: 09/594,577 | : Petition Decision |
| Filing Date: 15 June 2000 | : |
| Attorney Docket No. 000683 | : |

This letter is in response to the Petition under 37 CFR 1.181, filed on 8 January 2003 to require the examiner to reconsider entry of Amendment A, filed 12 August 2002. The delay in acting upon this petition is regretted.

BACKGROUND

This application was filed 30 claims, which the examiner restricted into three groups and set forth an election of species. See Paper No. 2, mailed 31 July 2001. In Paper No. 5, filed 14 March 2002, applicants elected Group I, drawn to a method for detecting carcinoembryonic antigens (CEAs) or a method for detecting cancer comprising using an antibody against a constant region of CEA and a protein capable of recognizing a modified sugar chain structure. Applicants also elected the anti-Le^a antibody for examination. The elected group and species, claims 1-4, 6-7, 12-13, 16 and 19, were examined in Paper No. 6, mailed 21 May 2002, resulting in rejections under 35 U.S.C. 112, 102 and 103.

Applicants responded by filing Amendment A, Paper No. 8, filed 12 August 2002, in which all claims were canceled and new claims 31-44 added. Claim 31 is the only

independent claim presented. Claims 32-43¹ are all properly dependent off of Claim 31 and are narrowed in scope by inclusion of additional limitations.

On 4 November 2002, the Office sent out a letter advising applicant that the amendment to cancel all claims drawn to the elected invention and presenting only claims directed to a non-elected invention is non-responsive, citing MPEP 821.03. The letter points to the additional method steps included in claims 31-33, the additional types of cancer and additional antibodies as reasons why the new claims do not read upon the elected invention.

On 6 January 2003, this petition was filed under 37 CFR 1.181. Applicant argues that each of the limitations added to new claims only narrow the scope of the claims and does not add claims drawn to a different invention.

The Petition also mentions a telephonic interview with the Examiner on 13 December 2002, however, the file fails to contain an examiner interview summary form.

DISCUSSION

A review of new claim 31 shows that it is directed in general to a method of detecting cancer using CEA antigen sugar chain structure as an indication for detection. This is comparable in scope to Group I's original claim 11.

New Claim 31 requires binding a protein that selectively binds to a sugar chain structure and an antibody against a constant region of carcinoembryonic antigens to form a complex and detecting the complex. This is comparable in scope to Group I's original claim 3.

New Claim 34, depends upon Claim 31 and contains the limitation that the first protein is an Anti-Le^a antibody. This is comparable in scope to Group I's original claim 7 and reads upon the elected species.

New Claims 31-33 differ from Original claim 1 by the recitation of additional second, third and fourth method steps, which are proper in view of the claim format and open claim language, a "method comprising." Each of these additional method steps narrow the scope of the claimed invention by requiring subsequent assays to detect additional complexes. The multiple method steps are required altogether in the claims, not options presented in the alternative.

New Claims 35 and 36 describe the second, third and fourth proteins to be assayed in the second, third and fourth method steps of Claims 31-33, respectively. The detection of

¹ As claim No. 36 was omitted in the amendment, claims 37-44, and their corresponding dependencies have been renumbered under Rule 1.126 to recite Claims 36-43, respectively. The claims will be referred to as renumbered under Rule 1.126.

cancer often relies upon multiple, sequential assay steps to determine the presence and absence of particular markers, which taken together, define the particular cancer types. A physician then bases any cancer diagnosis upon the combined results from various tests.

New Claims 37-43 specify the determination of rectal, colon, lung, liver, breast, cervix uteri and bone marrow lymph metastasis, respectively, by the various particular combinations of detectable and undetectable amounts of Anti-S-Le^a antibody, Anti-S-Le^x antibody, Anti-Le^a antibody, and Anti-S-Le^y antibody.

New Claims 31-33 are generic to the plurality of disclosed species of antibodies. Claims 34-43 all require the elected species Anti-Le^a.

As such, the new claims are directed to the elected invention and elected species.

DECISION

The Petition is **GRANTED** for the reasons set forth above. The letter mailed 4 November 2002 has been vacated. The amendment filed 12 August 2002 will be entered. The application will be returned to the Examiner for action addressing Amendment A and Response in a manner consistent with this petition decision.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, Washington DC 20231 or by telephone at (703) 308-7553 or by facsimile transmission at (703) 305-7230.

Jasemine C. Chambers
Jasemine Chambers
TC1600 Group Director